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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 02N–0451]

Withdrawal of 20 Guidances on Individual Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of 20 individual product labeling guidances. The guidances are being withdrawn because they are out of date and of little use to the generic drug industry. The agency has developed other guidance and resources to assist the industry in obtaining up-to-date labeling for reference listed drugs.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Rita Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION:

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I. Background

FDA is announcing the withdrawal of 20 individual product labeling guidances. A list of FDA's Center for Drug Evaluation and Research (CDER) guidances (the Comprehensive List) can be found on the Internet on the CDER guidance page at http://www.fda.gov/cder/guidance/index.htm, and many of the guidances on the Comprehensive List are posted on the CDER guidance page (old draft guidances have not been posted). This withdrawal of labeling guidances is in addition to the withdrawal of 53 individual product labeling guidances announced in the **Federal Register** of July 5, 2002 (67 FR 44857).

The labeling guidances being withdrawn were intended to provide sponsors of abbreviated new drug applications (ANDAs) with product specific templates for package insert labeling that could be submitted to the Office of Generic Drugs (OGD). Because package insert labeling for innovator products changes frequently, it is difficult to keep the guidances updated; and because these labeling guidances are out of date, they are being withdrawn.

In May 2000, the agency issued a guidance for industry entitled "Revising ANDA Labeling Following Revision of the RLD Labeling." This guidance provides information on how to access current package insert labeling on OGD's Labeling Review Branch Internet site at http://www.fda.gov/cder/ogd/rld/labeling_review_branch.htm.

The withdrawal of product-specific labeling guidances is part of a long-term effort in OGD to review guidance documents on the development of generic drug products with the goal of identifying documents that need to be revised, reformatted, or withdrawn because they are no longer current.

CDER is withdrawing the following labeling guidances:

Chlordiazepoxide Hydrochloride Capsules—January 1, 1988

Clorazepate Dipotassium Capsules/Tablets—March 1, 1993

Cyproheptadine Hydrochloride Tablets/Syrup—December 1, 1986

Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%—November 2, 1998

Ergoloid Mesylate Tablets—January 1, 1988

Hydroxyzine Hydrochloride Injection—December 1, 1989

Isoetharine Inhalation Solution—March 1, 1989

Meclofenamate Sodium Capsules—July 1, 1992

Naphazoline Hydrochloride Ophthalmic Solution—March 1, 1989

Niacin Tablets—July 1, 1992

Phendimetrazine Tartrate Capsules/Tablets, and Extended-Release Capsules—February 1, 1991

Phentermine Hydrochloride Capsules/Tablets—August 1, 1988

Promethazine Hydrochloride Tablets—March 1, 1990

Propantheline Bromide Tablets—August 1, 1988

Pyridoxine Hydrochloride Injection—June 1, 1984

Quinidine Sulfate Capsules USP—October 1, 1995

Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets—February 1, 1992

Theophylline Immediate Release Oral Dosage Forms—February 1, 1995

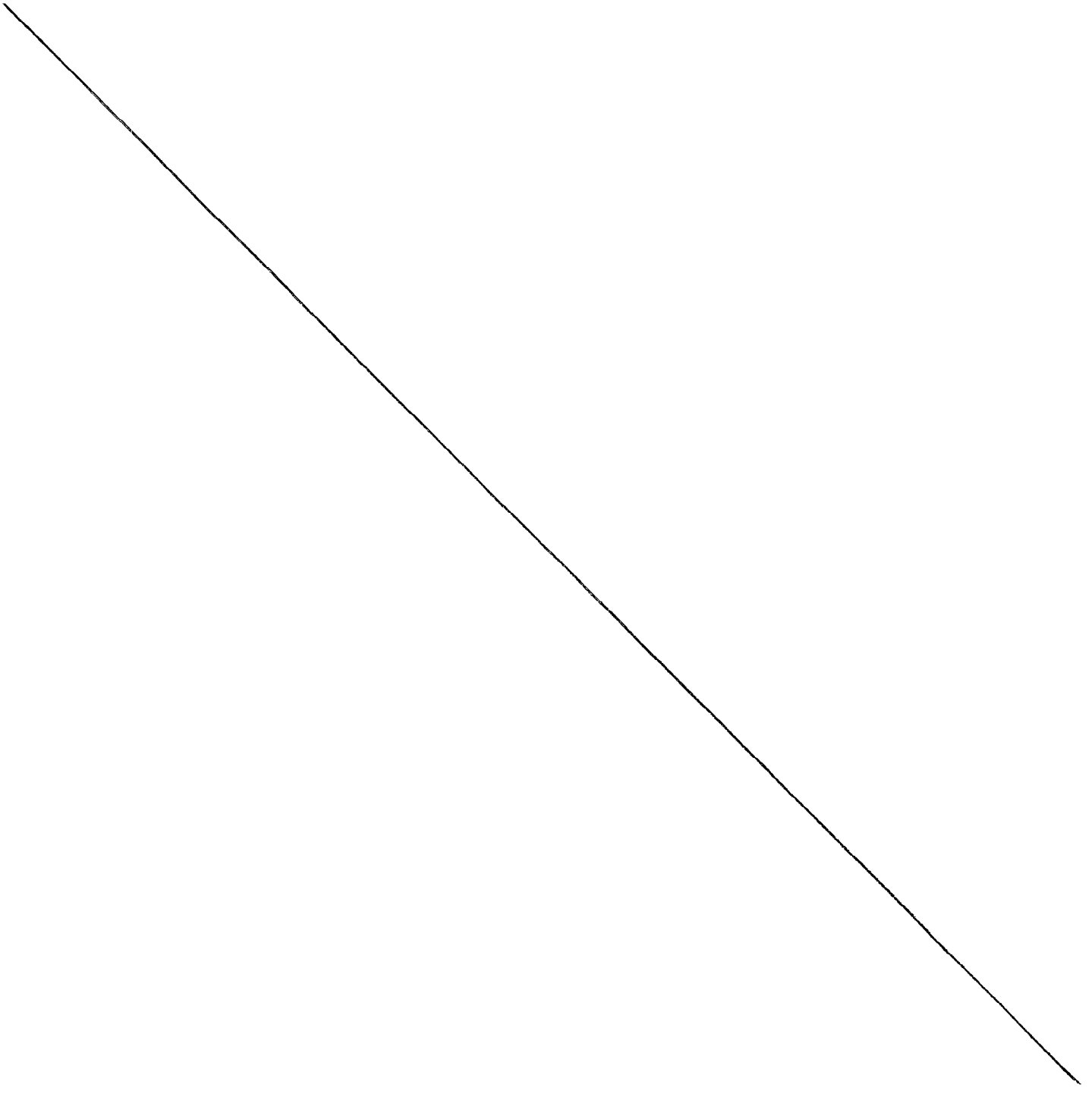
Thiamine Hydrochloride Injection—February 1, 1988

Vitamin A Capsules—February 1, 1992

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in

the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain guidance documents at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 11/25/02
November 25, 2002.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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